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		ART UNIT	PAPER NUMBER	
		1771		

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**JUL 15 2004**

**GROUP 1700**

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/489,473

Filing Date: January 21, 2000

Appellant(s): MATSUDA, KAZUHISA

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Ronald Kubovcik  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed March 17, 2004.

**(1) Real Party in Interest**

A statement identifying the real party in interest is contained in the brief.

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**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 1-14, not claims 1-15 as incorrectly stated by Applicant.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

**(7) *Grouping of Claims***

Appellant's brief includes a statement that claims 1-14 stand or fall together.

**(8) *ClaimsAppealed***

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) *Prior Art of Record***

USPN 5514181 to Light et al, and

USPN 5171273 to Silver et al.

**(10) *Grounds of Rejection***

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Light et al (5514181) in view of Silver et al (5171273).

The Light reference teaches a membrane for tissue regeneration comprising a nonwoven fabric, a film layer, and a sponge layer (fig. 2). Light teaches the film and sponge layer to be composed of either cross-linked hyaluronic acid or collagen (col. 3, lines 30-36 and 63-65., col. 4, lines 18-20). Light teaches the nonwoven layer to be composed of a number of different materials, but doesn't specifically mention collagen. Light, however, teaches that the nonwoven layer and film may be composed of the same materials (col. 4, lines 64-65). Light also teaches that cross linked collagen fibers are well known in the art and refers to the high strength synthetic fibers taught in Silver (col. 1, lines 35-65).

The Silver reference teaches a tissue graft. Silver teaches the use of synthetic collagen fibers (abstract) having applicant's claimed diameter (col. 7, lines 2-5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the synthetic collagen fibers of Silver to form the nonwoven layer of Light. The skilled artisan would have been motivated to utilize synthetic collagen fibers by the desire to obtain high-strength combined with beneficial wound healing properties (col. 2, lines 28-45 of Light and col. 2, lines 15-35 of Silver).

Light teaches a lyophilization process at col. 4, lines 2-5.

Light teaches the use of an acid at col. 5, line 14.

With respect to the claimed process limitations, it is the examiner's position that the membrane of light is identical to or only slightly different than the membrane prepared by the method of applicant, because both membranes are constructed of the same materials in a similar structure. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or an obvious variant from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show

unobvious differences between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983). The membrane of Light either anticipates or strongly suggests the claimed subject matter. It is noted that if the applicant intends to rely on Examples in the specification or in a submitted Declaration to show non-obviousness, the applicant should clearly state how the Examples of the present invention are commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with the membrane of Light.

With respect to claim 10, Light teaches that the collagen of the film Layer is embedded into the nonwoven layer (col. 3, lines 45-50). This would inherently act as a binder. This also reads on applicant's limitation that the nonwoven fabric be surrounded on all sides by a coating. With respect to applicant's claimed multiple layers, it would have been obvious to a person having ordinary skill in the art at the time the invention was made add additional layers of nonwoven material to the membrane of Light, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *ST. Regis Paper Co. V. Bemis co.*, 193 USPQ 8. Additional layers would increase the absorbency of Light's membrane. Light teaches applicant's claimed nonwoven thickness (col. 3, line 20). Silver teaches pressing the collagen material into varying dimensions and thicknesses (col. 11, lines 2-5). It would have been obvious to a person having ordinary skill in the art to compress the layers of Light. Such a modification would have been motivated by the desire to render the material suitable for a variety of different applications. Light is silent with respect to the bulk density of the nonwoven layer. If the nonwoven layer of Light does not inherently have a bulk density within applicant's claimed range then it would have been obvious to vary said density. The skilled artisan would have been motivated to vary the density of the material by the desire to optimize the absorbent properties of the material.

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**(11) Response to Argument**

Applicant has misconstrued the combination of Light and Silver. The Examiner's combination of references relies on Silver to modify only the foraminous layer of Light, thus not affecting the presence of hyaluronic acid or other components. Therefore, Applicant incorrectly attests that the result is a prostheses formed "solely" of collagen, when in fact the combination proposed in the rejection has a structure comprising a nonwoven fabric layer (Light) made of collagen (Silver), a film layer, and a sponge layer, both the film and sponge layer made of either cross-linked hyaluronic acid or collagen (Light). For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Arden B. Sperty  
Examiner  
Art Unit 1771

July 12, 2004

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